Approved Alternative Requirements

1. Conducting the daily processor QC tests when the sensitometer is not available

This alternative standard was approved on October 18, 1999 and was made retroactive to April 28, 1999. The alternative to sensitometric-densitometric testing of processor performance can be used for a period of up to two weeks when the facility's sensitometer is unavailable. This alternative is based on evaluating a phantom image through measurements described in 21 CFR 900.12(e)(1) and (2).

The final regulation and its alternative standard are stated below:

21 CFR 900.12(e)(1) and (2) states that:

(1) Daily quality control tests. Film processors used to develop mammograms shall be adjusted and maintained to meet the technical development specifications for the mammography film in use. A processor performance test shall be performed on each day that clinical films are processed before any clinical films are processed that day. The test shall include an assessment of base plus fog density, mid-density, and density difference, using the mammography film used clinically at the facility.

(i) The base plus fog density shall be within + 0.03 of the established operating level.

(ii) The mid-density shall be within +/- 0.15 of the established operating level.

(iii) The density difference shall be within +/- 0.15 of the established operating level.

(2) Weekly quality control tests. Facilities with screen-film systems shall perform an image quality evaluation test, using an FDA-approved phantom, at least weekly.

(i) The optical density of the film at the center of an image of a standard FDA-accepted phantom shall be at least 1.20 when exposed under a typical clinical condition.

(ii) The optical density of the film at the center of the phantom image shall not change by more than +/- 0.20 from the established operating level.

(iii) The phantom image shall achieve at least the minimum score established by the accreditation body and accepted by FDA in accordance with Sec. 900.3(d) or Sec. 900.4(a)(8).

(iv) The density difference between the background of the phantom and an added test object, used to assess image contrast, shall be measured and shall not vary by more than +/- 0.05 from the established operating level.

When using the alternative test, processor performance is considered satisfactory if:

1. The optical density of the film at the center of an image of a standard FDA-accepted phantom is at least 1.20 when exposed under typical clinical conditions.
2. The optical density of the film at the center of the phantom image changes no more than +/- 0.20 from the established operating level.

3. The density difference between the background of the phantom and an added test object, used to assess image contrast, is measured and does not vary by more than +/-0.05 from the established operating level.

In addition:

4. To evaluate base + fog, an additional measurement of density must be made either of a shielded portion of the phantom image film or of an unexposed film. In accordance with 21 CFR 900.12(e)(1)(i), the base plus fog density must be within + 0.03 of the established operating level.

This alternative test must be conducted "each day clinical films are processed, but before processing of clinical films." All results must be recorded and charted. If processor performance fails to meet any part of the alternative test, the problem must be corrected before processing is resumed.

2. Continuous display of the override status for machines with decompression devices

This alternative standard was approved on June 22, 1999 and was made retroactive to April 28, 1999. It has no time limit.

The final regulation and its alternative standard are stated below:

21 CFR 900.12(e)(5)(xi) states that:

(xi) Decompression. If the system is equipped with a provision for automatic decompression after completion of an exposure or interruption of power to the system, the system shall be tested to confirm that it provides:

(A) An override capability to allow maintenance of compression;

(B) A continuous display of the override status; and

(C) A manual emergency compression release that can be activated in the event of power or automatic release failure.

The approved alternative standard to 21 CFR 900.12(e)(5)(xi)(B) allows facilities having machines equipped with automatic decompression devices that are never disabled to permanently place a label on the panel indicating that the unit must always be operated in the automatic decompression mode, in lieu of a continuous display of the automatic decompression override status required in 21 CFR 900.12(e)(5)(xi)(B). The wording of this label must be:

Unit always to be used in auto release mode. If auto release is overridden this status will not be displayed.

3. Conducting the weekly phantom image test at facilities with intermittent mammography operation

This alternative standard was approved on May 24, 1999 and was made retroactive to April 28, 1999. It applies to facilities that do not conduct mammography every week. Rather, they may conduct mammography during some, but not all, weeks in a given month.

The final regulation and its alternative standard are stated below:

21 CFR 900.12(e)(2) states that:

> *(2) Weekly Quality Control Tests. Facilities with screen-film systems shall perform an image quality evaluation test, using a FDA-approved phantom, at least weekly.*

The approved alternative standard is:

(2) Weekly Quality Control Tests. Facilities with screen-film systems shall perform an image quality evaluation test, using an FDA-approved phantom, in each week that clinical mammography examinations are performed, prior to the performance of such examinations.

The alternative standard requires that if the number of weeks per month in which clinical mammography is performed increases or decreases, the frequency of the performance of the phantom image quality test must automatically undergo a corresponding increase or decrease. Because of this automatic adjustment to changing facility conditions, no time limit has been placed upon the period of approval.

4. Post exposure indication of the machine pre-selected focal spot and or target material

This alternative standard was approved on April 19, 1999 and became effective on April 28, 1999 for Senographe^{TM} DMR GE machines.

The final regulation and its alternative standard are stated below:

21 CFR 900.12(b)(7) states that:

> *(7) Focal spot selection.*
> *(i) When more than one focal spot is provided, the system shall indicate, prior to exposure, which focal spot is selected.*
> *(ii) When more than one target material is provided, the system shall indicate, prior to exposure, the preselected target material.*
> *(iii) When the target material and/or focal spot is selected by a system algorithm that is based on the exposure or on a test exposure, the system shall*

display, after the exposure, the target material and/or focal spot actually used during the exposure.

The approved alternative is:

(7) Focal spot selection.

(i) When more than one focal spot and/or more than one target material is provided, the system shall indicate, prior to exposure, the pre-selected focal spot and target material, and shall indicate, after the exposure, the focal spot and test material actually used during the exposure; or

(ii) When the target material and/or focal spot is selected by a system algorithm that is based on the exposure or on a test exposure, the system shall indicate, after the exposure, the target material and/or focal spot actually used during the exposure."

Under the approved alternative, an indication of the pre-exposure focal spot and target material would no longer be required when the pre-exposure target material and focal spot are set by a system algorithm based on exposure and the user has no control over that selection. In operating modes where the user has control of the pre-selected focal spot and/or target material, indication of the pre-selected values would still be required. In all cases, indication of the focal spot and/or target material actually used during the exposure would be required. (Note: # 5, #6 and #7 begin on next page)

5. Verification Testing After Certain Modifications of the AEC of Senographe ™ 700T, 800T, DMR Mammography Systems

This alternative standard was approved and became effective on September 24, 2001. Under this alternative, the verification perform after the specified AEC modifications may be performed under the conditions of Medical Physicist Oversight.

The final regulation and its alternative standard are stated below:

21 CFR 900.12(e)(10) states that:

> (10) *Mammography equipment evaluations.* Additional evaluations of mammography units or image processors shall be conducted whenever a unit or processor is installed, a unit or processor is dissembled and reassembled at the same or a new location, or major components of a mammography unit or processor equipment are changed or repaired. These evaluations shall be used to determine whether the new or changed equipment meets the requirements of applicable standards in paragraphs (b) and (e) of this section. All problems shall be corrected before the new or changed equipment is put into service for examinations or film processing. The mammography equipment evaluation shall be performed by a medical physicist or by an individual under the direct supervision of a medical physicist.

The approved alternative standard is:

For:

1. the modification of the AEC component of Senographe™ 700T or 800T mammography systems described in the GE Medical System's Field Modification Instruction (FMI) 11451, "Seno 700/800T Optical Density Optimization", and
2. the optimization of the AEC component of the Senographe™ DMR mammography systems described in the GE Medical System's FMI 11450, "CMR V1/V2+ Optical Density Optimization":

> Verification testing to demonstrate that the affected equipment meets the applicable standards must be carried out after these actions are completed. However, verification testing may be performed under Medical Physicist Oversight. Medical Physicist Oversight means that the medical physicist is consulted as to whether an on-site visit is required or if other personnel can verify that the standards are met, with direction by telephone or printed material from the medical physicist as needed.

6. Conducting the Mammography Equipment Evaluation After a Software Upgrade Under Medical Physicist Oversight

This alternative standard was approved and became effective on May 31, 2002. It defines the conditions under which the mammography equipment evaluations performed after **some** computer software upgrades may be performed either by a medical physicist on site or under the conditions of Medical Physicist Oversight. If these conditions are not met the mammography equipment evaluation after the upgrade must be performed by a medical physicist on site.

The original standard is contained within 21 CFR 900.12(e)(10) and is indicated by the italicized words below.

> (10) *Mammography equipment evaluations.* Additional evaluations of mammography units or image processors shall be conducted whenever a unit or processor is installed, a unit or processor is dissembled and reassembled at the same or a new location, or major components of a mammography unit or processor equipment are changed or repaired. These evaluations shall be used to determine whether the new or changed equipment meets the requirements of applicable standards in paragraphs (b) and (e) of this section. All problems shall be corrected before the new or changed equipment is put into service for examinations or film processing. *The mammography equipment evaluation shall be performed by a medical physicist or by an individual under the direct supervision of a medical physicist.*

The approved alternative and the conditions for its use are:

> Software changes or upgrades are considered by FDA to be major repairs, thus the facility must have a mammography equipment evaluation performed after installation of such a change or upgrade. The mammography equipment evaluation must be performed and all failures to meet the applicable standards must be corrected before the affected equipment is used for patient examinations. The tests to be included in the mammography equipment evaluation must be specified by the manufacturer. The specified tests must be adequate for determining whether all of the standards of 21 CFR 900.12(b) and (e) that are applicable to the upgrade are met. If the tests included in the mammography equipment evaluation are all tests that are performed by the quality control technologist as part of the quality assurance program required by the manufacturer, then the mammography equipment evaluation may be conducted either during an onsite visit by a medical physicist or under Medical Physicist Oversight. If any of the necessary tests after the software upgrade are required to be performed by the medical physicist, the mammography equipment evaluation must be performed in its entirety by the medical physicist on site.

Additional conditions for using this alternative requirement in association with a software upgrade are that:

1. The manufacturer must notify FDA of its intention to install the upgrade. The notification must include a brief description of the upgrade, the model(s) of the units that will be upgraded, and a copy of the information to be provided to each facility describing the upgrade and the facility's post installation responsibilities. The manufacturer must receive confirmation from FDA that the upgrade is covered by the alternative requirement before beginning installation.
2. By the completion of each individual upgrade, the manufacturer must inform the facility in writing of its post installation responsibilities under the alternative requirement, which are that the facility must:
   - conduct a mammography equipment evaluation after installation of the upgrade, either during a medical physicist onsite visit or under Medical Physicist Oversight,
   - include in its mammography equipment evaluation the tests specified by the manufacturer,
   - perform the mammography equipment evaluation and correct all test failures before the affected equipment is used for patient examinations, and
   - keep records of the test results and follow-up actions in accordance with 21 CFR 900.12(d)(2).

7. Correction Period When Components of the Senographe™ 2000D Full Field Digital Mammography (FFDM) System Fail Quality Control Tests

This alternative standard was approved and became effective on June 27, 2002. It allows a 30 day period for corrective actions following the failure of specified quality control tests by the Senographe™ 2000D FFDM system. The specified tests are equivalent to quality control tests for screen-film systems for which a 30 day correction period is already allowed. The alternative standard also divides into two groups the quality control tests whose failure requires corrective action before the failing component is used again during patient examinations. This division makes it clear that when the test failure is related to the acquisition of images only, the review of already acquired images can continue and when the test failure is related to the image review components only, images can continue to be acquired. The alternative was approved for an indefinite period.

The original standard is 21 CFR 900.12(e)(8)(ii), which states:

21 CFR 900.12(e)(8): *Use of test results*

(ii) If the test results fall outside of the action limits, the source of the problem shall be identified and corrective actions shall be taken:

(A) Before any further examinations are performed or any films are processed using the component of the mammography system that failed any of the tests, described in paragraphs (e)(1), (e)(2), (e)(4)(i), (e)(4)(iii), (e)(5)(vi), (e)(6), or (e)(7) of this section;

The approved alternative is:

21 CFR 900.12(e)(8): *Use of test results.*

(ii) If the test results for the Senographe™ 2000D FFDM fall outside of the action limits, the source of the problem shall be identified and corrective actions shall be taken:

(A) Before any further mammographic images are acquired using the Senographe™ 2000D FFDM system that failed any of the following tests:

(1) Monitor cleaning for the Acquisition Work Station (AWS)
(2) Flat Field Test
(3) CNR Test
(4) Phantom Image Quality Test for the AWS
(5) MTF Measurement
(6) AOP Mode and SNR Check
(7) Visual Check List
(8) Compression Force Test
(9) Average Glandular Dose
(10) Post-move, Pre-examination Tests for Mobile Senographe™ 2000D FFDM

(B) Before any further mammographic images are reviewed or interpreted or any films are printed or processed using the component of the Senographe™ 2000D FFDM system that failed any of the following tests:

(1) Monitor cleaning for the Review Work Station (RWS)
(2) Viewing Conditions for the RWS (Radiologic Technologist's test)
(3) Viewing Conditions Check and Setting (Medical Physicist's test for the RWS)
(4) Phantom Image Quality Test for the RWS
(5) Phantom Image Quality Test for the Printer
(6) Viewbox and Viewing Conditions Test
(7) Monitor Calibration Check (Radiologic Technologist's test for the RWS)
(8) Image Quality—SMPTE Pattern (Medical Physicist's test for the RWS)
(9) Printer QC

(C) Within 30 days of the test date for the following tests:

(1) Repeat Analysis
(2) Collimation Assessment
(3) Evaluation of Focal Spot Performance

(4) Exposure and mAs Reproducibility
(5) Artifact Evaluation; Flat Field Uniformity
(6) Monitor Calibration (Medical Physicist's test for the RWS)
(7) Analysis of the RWS Screen Uniformity
(8) kVp Accuracy and Reproducibility
(9) Beam Quality Assessment (Half-Value Layer Measurement)
(10) Radiation Output
(11) Mammographic Unit Assembly Evaluation

8. Combined Mammography Medical Outcomes Audit for Multiple Mobile Mammography Units

FDA approved this alternative standard on November 4, 2002 and amended it on December 3, 2002. The amended alternative standard became effective on the latter date. Some accreditation bodies accredit each mobile unit separately, even if two or more units are under the same ownership. This approach leads to each mobile unit being certified as a separate facility. Therefore, before the alternative requirement became effective, a separate mobile medical outcomes audit had to be performed for each unit. This alternative allows owners of multiple mobile mammography units to perform a combined mammography medical outcomes audit for all of the units if the specified conditions are met.

The original standard is 21 CFR 900.12(f)(1), which states:

> 21 CFR 900.12(f)(1): General requirements. Each facility shall establish a system to collect and review outcome data for all mammograms performed, including follow-up on the disposition of all positive mammograms and correlation of pathology results with the interpreting physician's mammography report. Analysis of these outcome data shall be made individually and collectively for all interpreting physicians at the facility. In addition, any cases of breast cancer among women imaged at the facility that subsequently become known to the facility shall prompt the facility to initiate follow-up on surgical and/or pathology results and review of the mammograms taken prior to the diagnosis of a malignancy.

The approved alternative, as amended, is:

> 21 CFR 900.12(f)(1): General requirements. Each facility shall establish a system to collect and review outcome data for all mammograms performed, including follow-up on the disposition of all positive mammograms and correlation of pathology results with the interpreting physician's mammography report. Analysis of these outcome data shall be made individually and collectively for all interpreting physicians at the facility. In addition, any cases of breast cancer among women imaged at the facility that subsequently become

known to the facility shall prompt the facility to initiate follow-up on surgical and/or pathology results and review of the mammograms taken prior to the diagnosis of a malignancy. In situations where multiple mobile mammography facilities are under the same ownership, they may be treated collectively as a single "facility" for the purposes of meeting these requirements, if all of the following conditions are met.

(i) Each facility must consist of a single mobile mammography unit.

(ii) The same entity or group administers the operation of all of the included mobile facilities.

(iii) The same lead interpreting physician has the responsibility for assuring that all of the included mobile facilities meet the requirements of 21 CFR 900.12(d) through (f).

(iv) The same group of radiologists read all of the images from all of the included mobile facilities.

(v) All of the included mobile facilities provide services to the same patient population.

9. Separate Assessment of Findings For Each Breast

FDA approved this alternative standard on July 3, 2003. It became effective on that date. It allows the interpreting physician to provide a separate assessment of findings for each breast in the medical report, without the need to also provide an overall assessment of findings. Therefore, the interpreting physician can choose between providing separate assessments under this alternative or providing an overall assessment for the examination under the original standard. The alternative was approved for an indefinite period.

The original standard is 21 CFR 900.12(c)(1)(iv), which states:

> 21 CFR 900.12(c)(1): *Medical records and mammography reports*
> …..
> (iv) Overall assessment of findings, classified in one of the following categories:

Your requested alternative is:

> 21 CFR 900.12(c)(1): *Medical records and mammography reports*
> …
> (iv) A separate assessment of findings for each breast, classified in one of the following categories:

The conditions of use of this alternative are that:

- a single medical report covering the assessment of both breasts will be sent to the referring physician (or to the patient if there is no referring physician);
- a single lay report will be sent to the patient, containing information based on the overall assessment for both breasts; and
- even though separate assessments are made for each breast, the interpretation will count as only one examination towards meeting the MQSA experience requirements and will be billed as a single examination.

10. Correction Period When Components of the Selenia Full Field Digital Mammography System Fail Quality Control Tests

FDA approved this alternative requirement on August 21, 2003 and it became effective on that date. It allows a 30 day period for corrective actions following the failure of specified quality control tests by the Selenia Full Field Digital Mammography System. The specified tests are equivalent to quality control tests for screen-film systems for which a 30 day correction period is already allowed. The alternative standard also divides into two groups the quality control tests whose failure requires corrective action before the failing component is used again during patient examinations. This division makes it clear that when the test failure is related to the acquisition of images only, image acquisition must cease until the problem is corrected but image interpretation can

continue. Similarly if the test failure is related to the interpretation of images, image acquisition can continue but image interpretation with the failed component must cease until the problem is corrected. The alternative was approved for an indefinite period.

The original standard is 21 CFR 900.12(e)(8)(ii), which states:

> 21 CFR 900.12(e)(8): *Use of test results*
> (ii) If the test results fall outside of the action limits, the source of the problem shall be identified and corrective actions shall be taken:
> (A) Before any further examinations are performed or any films are processed using the component of the mammography system that failed any of the tests, described in paragraphs (e)(1), (e)(2), (e)(4)(i), (e)(4)(iii), (e)(5)(vi), (e)(6), or (e)(7) of this section;

The approved alternative is:

> 21 CFR 900.12(e)(8): Use of test results.
> (ii) If the test results for the Selenia FFDM System fall outside the action limits, the source of the problem shall be identified and corrective actions shall be taken:
> (A) If any of the following quality control tests that evaluate the performance of the image acquisition components of the Selenia FFDM system produces results that fall outside the action limits as specified by the manufacturer, the source of the problem shall be identified and corrective action shall be taken before any further examinations are performed:
> (1) Evaluation of System Resolution
> (2) Breast Entrance Exposure and Average Glandular Dose
> (3) Phantom Image Quality Evaluation (Medical Physicist)
> (4) Phantom Image (Radiologic Technologist)
> (5) Signal-to-Noise and Contrast-to-Noise Measurements
> (6) Detector Flat-Field Calibration
> (7) Compression
> (8) Post-Move and Pre-Examination Tests for Mobile Selenia™ FFDM systems
>
> (B) If any of the following quality control tests that evaluate the performance of a *diagnostic device used for mammographic image interpretation* (i.e. laser printer, physician's review station) produces results that fall outside the action limits as specified by the manufacturer, the source of the problem shall be identified and corrective action shall be taken before that device can be used for mammographic image interpretation.

Clinical imaging can be continued and alternative approved diagnostic devices shall be used for mammographic image interpretation:

(1) Phantom Image Quality Evaluation (Medical Physicist)
(2) Phantom Image (Radiologic Technologist)
(3) Softcopy Workstation QC
(4) Laser Printer Quality Control
(5) Dark Room Cleanliness
(6) Processor Quality Control
(7) Viewboxes and Viewing Conditions
(8) Darkroom Fog

(C) If any of the following quality control tests that evaluate the performance of *components <u>other</u> than the digital image receptor or the diagnostic devices used for mammographic image interpretation* produces results that fall outside the action limits as specified by the manufacturer, the source of the problem shall be identified and corrective action shall be taken within thirty days of the test date. Clinical imaging and mammographic image interpretation can be continued during this period:

(1) Mammographic Unit Assembly Evaluation
(2) Collimation Assessment
(3) Artifact Evaluation
(4) kVp Accuracy and Reproducibility
(5) Beam Quality Assessment – HVL Measurement
(6) Radiation Output Rate
(7) Viewbox Luminance and Room Illuminance
(8) Compression Threshold Indicator
(9) Visual Checklist
(10) Analysis of Fixer Retention in Film
(11) Repeat Analysis

11. Amendment to the Alternative Requirement for the Correction Period When Components of the SenographeTM 2000D Full Field Digital Mammography (FFDM) System Fails Quality Control Tests

FDA approved an amendment to Alternative Standard No. 7 (see above) on August 25, 2003. The amendment became effective on that date and no time limit has been placed upon the period of approval. The amended standard replaces the specific reference to the GE Senographe^{TM} 2000D FFDM system with a generic reference to an "FDA-approved GE" FFDM system. Like the original standard, it allows a 30 day period for corrective actions following the failure of specified quality control tests by an FDA-approved GE

FFDM system. However, it divides into two groups the tests whose failure requires corrective action before the failing component is used again during patient examinations. This division makes it clear that when the test failure is related to the acquisition of images only, the review of already acquired images can continue and when the test failure is related to the image review components only, images can continue to be acquired. In approving the amendment, FDA stated that if GE introduces new FFDM systems having QC tests other than what is included in the original or amended standard, the amended alternative standard would not be applicable to such systems.

The original approved alternative standard is an alternative to 21 CFR 900.12(e)(8)(ii) and states:

21 CFR 900.12(e)(8): *Use of test results*.

(ii) If the test results for the Senographe™ 2000D FFDM fall outside of the action limits, the source of the problem shall be identified and corrective actions shall be taken:

(A) Before any further mammograms are acquired using the Senographe™ 2000D FFDM system that failed any of the following tests:

(1) Monitor cleaning for the Acquisition Work Station (AWS)
(2) Flat Field Test
(3) CNR Test
(4) Phantom Image Quality Test for the AWS
(5) MTF Measurement
(6) AOP Mode and SNR Check
(7) Visual Check List
(8) Compression Force Test
(9) Average Glandular Dose
(10) Post-move, Pre-examination Tests for Mobile Senographe™ 2000D FFDM

(B) Before any further examinations are reviewed or any films are printed or processed using the component of the Senographe™ 2000D FFDM system that failed any of the following tests:

(1) Monitor cleaning for the Review Work Station (RWS)
(2) Viewing Conditions for the RWS (Radiologic Technologist's test)
(3) Viewing Conditions Check and Setting (Medical Physicist's test for the RWS)
(4) Phantom Image Quality Test for the RWS
(5) Phantom Image Quality Test for the Printer
(6) Viewbox and Viewing Conditions Test
(7) Monitor Calibration Check (Radiologic Technologist's test for the RWS)
(8) Image Quality—SMPTE Pattern (Medical Physicist's test for the RWS)
(9) Printer QC

(C) Within 30 days of the test date for the following tests:

(1) Repeat Analysis
(2) Collimation Assessment
(3) Evaluation of Focal Spot Performance
(4) Exposure and mAs Reproducibility
(5) Artifact Evaluation; Flat Field Uniformity
(6) Monitor Calibration (Medical Physicist's test for the RWS)
(7) Analysis of the RWS Screen Uniformity
(8) kVp Accuracy and Reproducibility
(9) Beam Quality Assessment (Half-Value Layer Measurement)
(10) Radiation Output
(11) Mammographic Unit Assembly Evaluation

The approved amendment to this alternative is:

21 CFR 900.12(e)(8): *Use of test results*.

For the image acquisition system

(i) If the test results for the image acquisition system of the FDA-approved GE full-field digital mammography (FFDM) equipment fall outside of the action limits, the source of the problem shall be identified and corrective actions shall be taken:

(A) Before any further mammographic images are acquired using the image acquisition system that failed any of the following tests:

(1) Monitor cleaning for the acquisition work station (AWS)
(2) Flat Field Test
(3) CNR Test
(4) Phantom Image Quality Test for the AWS
(5) MTF Measurement
(6) AOP Mode and SNR Check
(7) Visual Check List
(8) Compression Force Test
(9) Average Glandular Dose
(10) Post-move, Pre-examination Tests for a mobile FDA-approved GE FFDM

(B) Before any further films of mammographic images are printed or processed using the component of the FDA-approved GE FFDM equipment that failed any of the following tests:

(1) Phantom Image Quality Test for the Printer
(2) Viewbox and Viewing Conditions Test
(3) Printer QC

(C) Within 30 days of the test date for the following tests:

(1) Repeat Analysis
(2) Collimation Assessment

(3) Evaluation of Focal Spot Performance
(4) Exposure and mAs Reproducibility
(5) Artifact Evaluation; Flat Field Uniformity
(6) kVp Accuracy and Reproducibility
(7) Beam Quality Assessment (Half-Value Layer Measurement)
(8) Radiation Output
(9) Mammographic Unit Assembly Evaluation

For the image display system

(ii) If the test results for the image display system of the FDA-approved GE full-field digital mammography (FFDM) equipment fall outside of the action limits, the source of the problem shall be identified and corrective actions shall be taken:

(A) Before any further mammographic images are reviewed or any films are printed or processed using the component of the image display system that failed any of the following tests:

(1) Monitor cleaning for the review workstation (RWS)
(2) Viewing Conditions for the RWS (Radiologic Technologist's test)
(3) Viewing Conditions Check and Setting (Medical Physicist's test for the RWS)
(4) Phantom Image Quality Test for the RWS
(5) Phantom Image Quality Test for the Printer
(6) Viewbox and Viewing Conditions Test
(7) Monitor Calibration Check (Radiologic Technologist's test for the RWS)
(8) Image Quality—SMPTE Pattern (Medical Physicist's test for the RWS)
(9) Printer QC

(B) Within 30 days of the test date for the following tests:

(1) Monitor Calibration (Medical Physicist's test for the RWS)
(2) Analysis of the RWS Screen Uniformity.

12. Modifications in the Assessment Categories Used in Medical Reports

FDA approved two alternative requirements dealing with the content of the medical report on August 29, 2003. They became effective on that date. One of these adds a new assessment category for use in the reports of the mammography examinations and also adds clarifying language to the existing assessment categories. The second adds a reference to the possible need to obtain prior mammograms in order to make a final assessment. The alternatives were approved for an indefinite period.

The original standards are 21 CFR 900.12(c)(1)(iv) and (v), which state:

21 CFR 900.12(c)(1): *Medical records and mammography reports*

…..
(iv) Overall assessment of findings, classified in one of the following categories:
(A) "Negative:" Nothing to comment upon (if the interpreting physician is aware of clinical findings or symptoms, despite the negative assessment, these shall be explained)";
(B) "Benign:" Also a negative assessment;
(C) "Probably Benign:" Finding(s) has a high probability of being benign;
(D) "Suspicious:" Finding(s) without all the characteristic morphology of breast cancer but indicating a definite probability of being malignant;
(E) "Highly suggestive of malignancy:" Finding(s) has a high probability of being malignant:
(v) In cases where no final assessment category can be assigned due to incomplete work-up, "Incomplete: Need additional imaging evaluation" shall be assigned as an assessment and reasons why no assessment can be made shall be stated by the interpreting physician; and

The approved alternatives are:

21 CFR 900.12(c)(1): *Medical records and mammography reports*
…..

(iv) Overall assessment of findings, classified in one of the following categories:
(A) "Negative:" Nothing to comment upon (if the interpreting physician is aware of clinical findings or symptoms, despite the negative assessment, these shall be explained)";
(B) "Benign Finding(s):" Also a negative assessment;
(C) "Probably Benign Finding(s):" Initial short-interval follow-up suggested. Finding(s) has a high probability of being benign;
(D) "Suspicious Abnormality:" Biopsy should be considered. Finding(s) without all the characteristic morphology of breast cancer but indicating a definite probability of being malignant;
(E) "Highly suggestive of malignancy:" Appropriate action should be taken. Finding(s) has a high probability of being malignant:
(F) "Known Biopsy Proven Malignancy:" Appropriate action should be taken.
(v) In cases where no final assessment category can be assigned due to incomplete work-up, "Incomplete: Need additional imaging evaluation and/or prior mammograms for comparison" shall be assigned as an assessment and reasons why no assessment can be made shall be stated by the interpreting physician; and

As was the case with the original standard, only the words in quotation marks are required to be included in the medical report when giving the assessment category or indicating that no final category can be assigned at the present time. The remaining language is intended to provide explanations of the categories in order to promote their

consistent use. It is not required to be included in the medical report, although the interpreting physician may do so if he or she wishes.